K113306

1. 510(k) Summary - Basic Information

JUL 16 2012

1.1 Submitter

Submitter: Bionet Co., LTD

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Date Prepared: October 7, 2011

1.2 Device Name

Device Name: *Cardio7*
Common Name: Electrocardiograph
Classification Name: Electrocardiograph (870.2340, Class II)

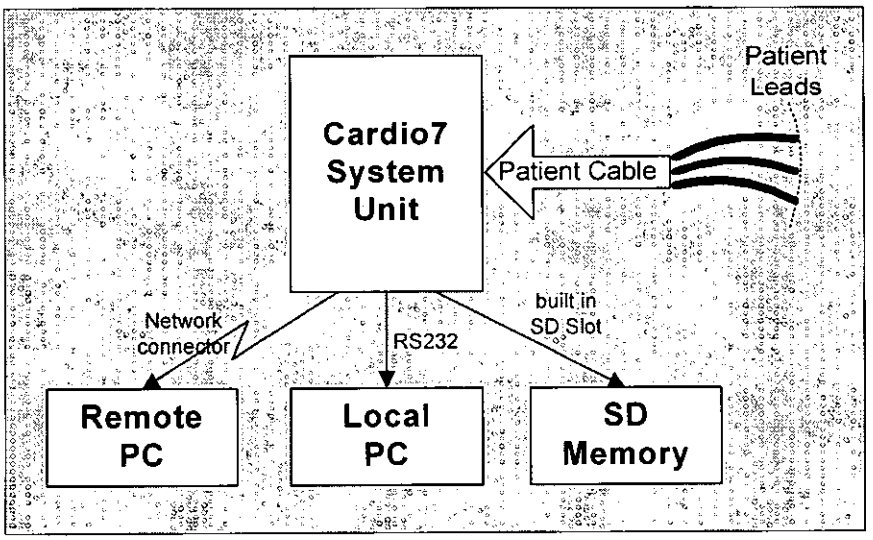
1.3 Identification of Legally Marketed Device

Substantial equivalence is claimed to the Bionet CardioXP (K102767).

1.4 Device Description

Cardio7 is an EKG monitoring system that provides standard EKG and (optional) pulmonary diagnostic functions. It offers enhanced usability, data analysis and data management. It consists of the several components depicted in Figure 1 that perform EKG and pulmonary monitoring, data analysis and data management functions.

Figure 1: Cardio7 Block Diagram Depiction



1.5 Intended Use

Cardio7 is intended for use as a diagnostic tool by trained operators in health facilities. It provides the following functions:

- Acquire ECG waveform data from up to twelve (12) leads through surface electrodes adhered to the patient's body.
- Input patient data.
- View, store and print captured data.
- Analyze captured data; display and print analysis results.
- Retain captured data and analysis results for up to 120 patients.
- Transfer retained data to a PC (via server IP) or directly to insertable USB Memory.

1.6 Comparison to Cleared Device

Table 1 compares the relevant features of *Cardio7* to the Bionet CardioXP (K102767).

Table 1: Comparison of Cardio7 to Predicate Device (CardioXP)

	CardioXP	**Cardio7**
Operating Principle	electrocardiographs	same
Target Population	Adult and pediatric patients	same
ECG Acquisition	Simultaneous 12 leads resting ECG connects to Patient Signal Module. CardioXP System Unit receives data from Patient Signal Module using either (1) direct cable connection or (2) Bluetooth communication.	Simultaneous 12 leads resting ECG connect directly to Cardio7 System Unit.
Basic measurement	Heart rate, PR int, QRS dur, QT/OTc, P-R-T axis	same
Sampling Rate	500 samples/sec/channel	same
Filters	• AC (50/60 Hz, -20dB or better), • Muscle (25~35Hz, -3dB or better), • Base line drift (0.1Hz, -3dB or better), • Low pass filter(off, 40Hz, 100Hz, 150Hz)	same
Display Type	built in color LCD	same
Display Functions	View and adjust ECG waveforms.	same
Monitor display	ID, HR, Sensitivity, Speed, Date, Power status	HR, ID, date, AC or Battery state, sensitivity, speed, number of saved data, printing form, rhythm lead
Patient Data	ID, name, age, birth, gender, height, weight, smoke, department, room number, race	ID, name, age, sex, height, weight, smoke, race
User Input	touch screen and rotary push-knob	same
Signal quality control	Disconnected lead detection. Pacemaker pulse detection	same
Data Storage	• Internal storage for up to 120 ECG • Additional storage available using built in SD RAM slot	same
Weight	Approx. 4 kg (8.8 lb)	Approx. 3.5 kg (7.7 lb)
Dimensions	300 x 299 x 123mm (11.8 x 11.8 x 4.8 in)	296 x 305 x 92 mm (11.7 x 12 x 3.6 in)
Power Source	AC power supply (95 ~ 240 VAC, 50/60Hz, 60 VA max) or battery power.	same

	CardioXP	Cardio7
Battery	• 3 hours of normal use or print 300 ECG pages. • Battery recharge to full capacity in 8 hours.	• 1 hours of normal use or print 100 ECG pages. • Battery recharge to full capacity in 4 hours.
Sterility	Wipe exterior of patient cable and electrocardiograph with damp cloth using mild detergent diluted in water. Disinfect patient cable using damp cloth of chemical disinfectants containing one of the following: • ethanol (70% - 80%) • propanol (70% - 80%) • aldehydes (2% - 4%)	same
Safety	Recognized and applicable standards: • EC11 (AAMI/ANSI) • IEC 60601-1-1 • IEC 60601-1-2 • IEC 60601-1-4 • IEC 60601-1-6 • IEC 60601-1-8 • IEC 60601-2-25 • ISO 10993-1:2003 • ISO 14971:2007 • ETSI EN 301 489 • ETSI EN 300 328 • EN 60950-1	Recognized and applicable standards: • EC11 (AAMI/ANSI) • IEC 60601-1-1 • IEC 60601-1-2 • IEC 60601-1-4 • IEC 60601-1-6 • IEC 60601-1-8 • IEC 60601-2-25 • ISO 10993-1:2003 • ISO 14971:2007
Printer	Thermal printer (internal)	same
Network Connection	Hardwired Ethernet	same
Indication for Use	The CardioXP electrocardiograph is one of the tools that clinicians can use to evaluate and diagnose patient cardiac function. The 12-lead ECG interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information.	same

1.6.1 Differences between Cardio7 and CP200

The meaningful differences between *Cardio7* and CardioXP are the method of ECG data acquisition and the availability of an external monitor.

- Whereas CardioXP acquires ECG data from its Patient Signal Module, *Cardio7* acquires ECG data directly from the Patient Cable. (CardioXP's Patient Signal Module is capable of transmitting ECG data to its system unit from a distance via wireless Bluetooth communication).
- CardioXP provides for an external monitor and *Cardio7* does not.

2. Performance Information

Because *Cardio7* complies with the EC11 standard, assessment of performance data is not necessary to determine of Substantial Equivalence for this type of device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 16 2012

Bionet Co., Ltd.
c/o Marc Goodman
Regulatory Consultant
5405 Alton Parkway 5A, #530
Irvine, CA 92604-3718

Re: K113306
Trade/Device Name: Cardio7
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: July 5, 2012
Received: July 9, 2012

Dear Mr. Goodman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number
(if known)

Device Name Cardio7

Indications for Use

The Cardio7 electrocardiograph is one of the tools that clinicians can use to evaluate and diagnose patient cardiac function. The 12-lead ECG interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113306